DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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April 5, 2017

Stryker Sustainability Solutions
Ms. Chelsea Cullen
Sr. Regulatory Affairs Specialist
1810 W Drake Drive
Tempe, Arizona 85283

Re: K170456
Trade/Device Name: Reprocessed HARMONIC FOCUS Shears + Adaptive Tissue Technology
Regulatory Class: Unclassified
Product Code: NLQ
Dated: February 13, 2017
Received: February 15, 2017

Dear Ms. Cullen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Models Subject to Clearance:

Model Number	Device Name/Description	Device Length	Active Blade Length
HAR9F	HARMONIC FOCUS® Shears + Adaptive Tissue Technology	9cm	16mm

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170456

Device Name
Reprocessed HARMONIC FOCUS® Shears + Adaptive Tissue Technology

Indications for Use *(Describe)*
The Reprocessed HARMONIC FOCUS® Shears + Adaptive Tissue Technology are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, otorhinolaryngologic (ENT), plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures (such as spine and joint space) and other open procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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SECTION 5: 510(k) SUMMARY

Submitter:
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Contact:
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Date of Preparation: February 13, 2017

Name of Device:

Trade/Proprietary Name: Reprocessed HARMONIC FOCUS® Shears + Adaptive Tissue Technology

Model Number: HAR9F

Common Name: Scalpel, Ultrasonic, Reprocessed

Classification Information: Class: Unclassified
Unclassified Reason: Pre-Amendment
Product Code: NLQ

Predicate Devices:

Model Number	510(k) Number	510(k) Title	Original Manufacturer
HAR9F	K133314	HARMONIC FOCUS® Shears + Adaptive Tissue Technology	Ethicon Endo-Surgery

Device Description:

Reprocessed HARMONIC FOCUS® Shears + Adaptive Tissue Technology are a sterile, single patient use instrument consisting of a soft grip scissor handle housing assembly with two hand controls (MIN for minimum power level and MAX for maximum power level). The instrument has a curved blade and clamp arm with Teflon pad. The instrument is 9 cm in length with a 16 mm active blade length. The Reprocessed HARMONIC FOCUS®+ Shears instrument allows for the cutting and coagulation of vessels up to and including 5 mm in diameter.

Each Reprocessed HARMONIC FOCUS®+ Shears instrument is packaged with one sterile, single patient use, disposable Torque Wrench.

Intended Use:

Reprocessed HARMONIC FOCUS® Shears + Adaptive Tissue Technology are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, otorhinolaryngologic (ENT), plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures (such as spine and joint space) and other open procedures.

Summary of Technological Characteristics:

The Reprocessed HARMONIC FOCUS Shears + Adaptive Tissue Technology use an EEPROM memory chip that stores device identification, usage tracking, and operating parameters for use by the Generator G11 that provides power for the HARMONIC FOCUS Shears + Adaptive Tissue Technology. Adaptive Tissue Technology refers to the advanced algorithms that allow the generator to communicate with the device and properly respond to the changing tissue conditions. The design, materials, and intended use of the reprocessed device are equivalent to the predicate device. The mechanism of action of the reprocessed device is identical to the predicate device in that the same standard mechanical design, materials, and sizes is utilized. The differences between the predicate device and the reprocessed device include a replacement Torque Wrench and replacement tissue pad. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation. In addition, Stryker Sustainability Solutions' reprocessing of the HARMONIC FOCUS® Shears + Adaptive Tissue Technology includes removal of adherent visible soil and decontamination. Each individual device is tested for appropriate function of its components prior to packaging and labeling operations.

Performance Data:

Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of Reprocessed HARMONIC FOCUS® Shears + Adaptive Tissue Technology. This included the following tests:

- Biocompatibility
- Validation of Reprocessing
- Sterilization Validation
- Functional Performance Tests
- Electrical Safety Testing
- Electromagnetic Compatibility Testing
- Packaging Validation

The functional performance testing involved electrical safety and electromagnetic compatibility testing in accordance with IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-2, and verification/comparative testing (to the predicate device). The bench testing involved evaluation of the device's performance and ability to seal and divide vessels up

to 5mm, including: thermal spread, transection time, burst pressure, device functionality, and device reliability.

Additionally, preclinical laboratory evaluations in an animal model were performed, which included acute and chronic survival studies. The studies were done to evaluate thermal spread and the ability to achieve hemostasis of vessels of the reprocessed device. The results of the evaluations demonstrate that the Reprocessed HARMONIC FOCUS Shears + Adaptive Tissue Technology effectively cut and coagulated vessels 1 to 5mm in diameter.

The performance testing demonstrates that reprocessed devices are as safe and effective as the predicate and operate as originally intended.

Conclusion:

The results of bench testing and preclinical laboratory evaluations demonstrate that the Reprocessed HARMONIC FOCUS® Shears + Adaptive Tissue Technology are at least as safe and effective and perform as well as the identified legally marketed predicate device as described herein.